

# Scinomed's New Plasmapheresis Platform. Does it deliver...?

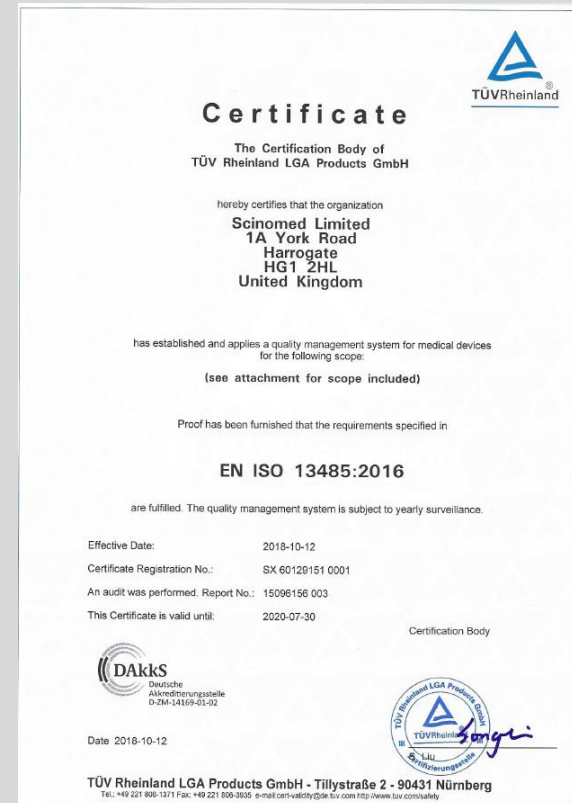
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# Who is Scinomed?

- Private Ltd Company registered in Harrogate in UK in 2008
- Business focused on manufacturing and marketing products to serve the blood transfusion and blood processing industry with initial emphasis on source plasma for fractionation
- Scinomed's values:
  - Maintain the highest standards in safety, quality and reliability
  - Maintain the highest ethical standards in all business practices
  - Identify opportunities to supply products and services which can add value
  - Recognise the value of relationships and people in our activities
  - Provide industry leading customer service and deliver as promised

- Scinomed is committed to delivering safe, reliable and effective medical products and services which add value and represent the highest quality standards.
- The organisation is committed to continually improving the effectiveness of the quality management system, setting quality objectives and reviewing quality performance.
- The organisation commits to comply with the ISO13485 quality management system standard for medical devices, statutory and legal requirements

- Scinomed Ltd has an ISO 13485 certified Quality Management System (by TÜV Rheinland)
- CE Mark for products and manufacturing (by TÜV Rheinland)
- Plasma collection machine qualified at 2018 safety standards



- Reliance on volunteer donors
- Safety and efficacy – for donor, patient and operator
- New technology and change – end to end process, importance of GMP
- Supply chain & business continuity planning
- Confidence in quality and reliability of supply
- Risk and uncertainty
- Next 5 to 10 years





## The New Platform

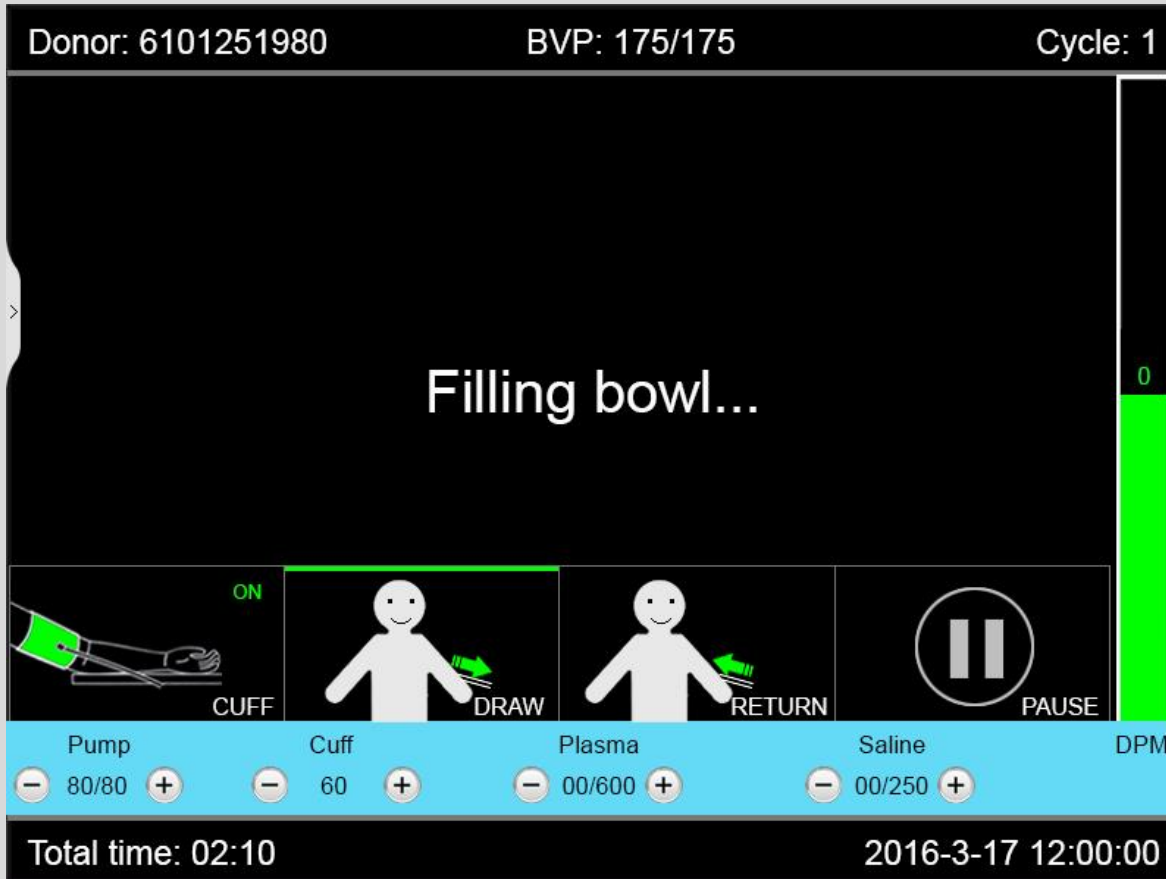


# Plasma Collection Machine: Main Features



- Mode of action:
  - Collection of plasma by automated separation from whole blood by centrifugation
- Main Features:
  - High definition LCD display touch screen
  - Alarm indicator with 360° viewing angle
  - Donor information screens – left/right side
  - Barcode/ RFID scanner
  - Auto loading pumps with 3 rollers
  - Advanced air detectors and blood flow monitors
  - Advanced optical sensors for cellular detection
  - Advanced plasma weigher
  - Machine operates stand alone or in bi-directional communication with donor management systems
  - System self test after each procedure

# Touch-Display as Interface to Operators



- The screen...
  - guides operators through set-up of the device
  - informs operators on the status of the procedure like filling bowl, drawing, returning, ...
  - Operators can stop procedure at any time and adjust settings, like pump speed , cuff pressure
  - indicates the reason potential alarms
  - in bi-directional communication with DMS will additionally display relevant information between device and DMS, like:
    - Operator-ID
    - Disposables released?
    - Donor released for donation?

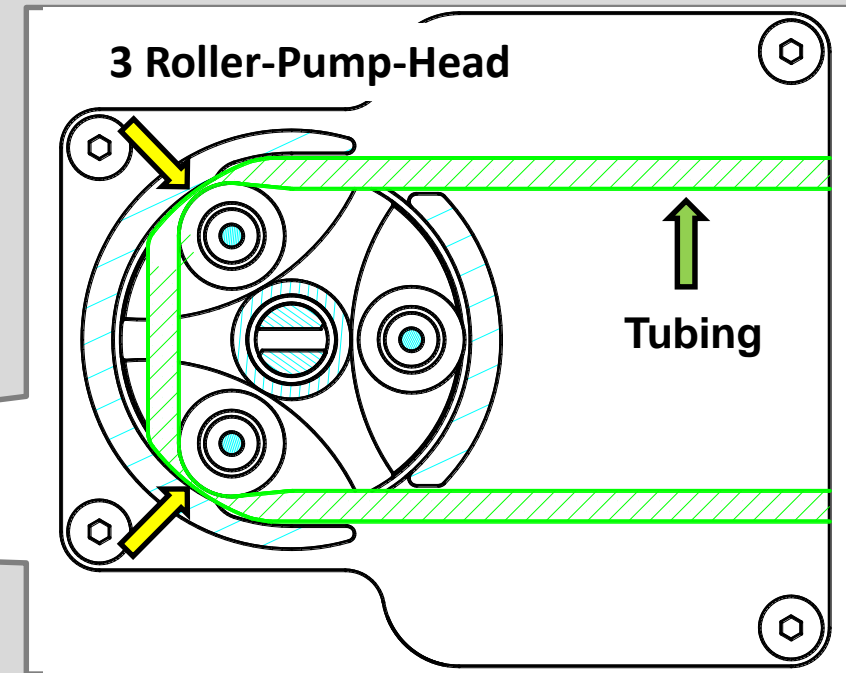


# Roller-Pumps



- Brushless servo motors
  - very accurate speed, low noise
  - overload protection for safety

# Triple Roller Design



- High accuracy smooth flow due to continuous contact of rollers with housing

Scan the operator barcode/RFID

Operator barcode/RFID: 8101251960

Clear barcode

Proceed

2016-3-17 12:00:00



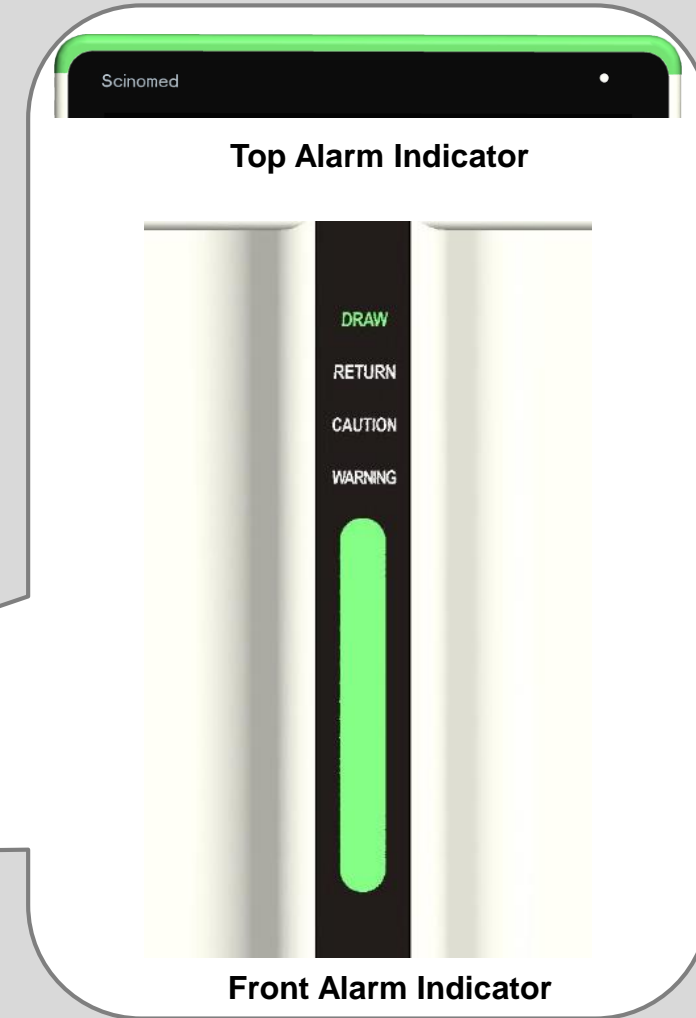
- Reads barcodes, like:
  - Disposable lot numbers
  - Operator ID
  - Donor ID
  - Unexpected events

# Bi-Directional Communication with DMS



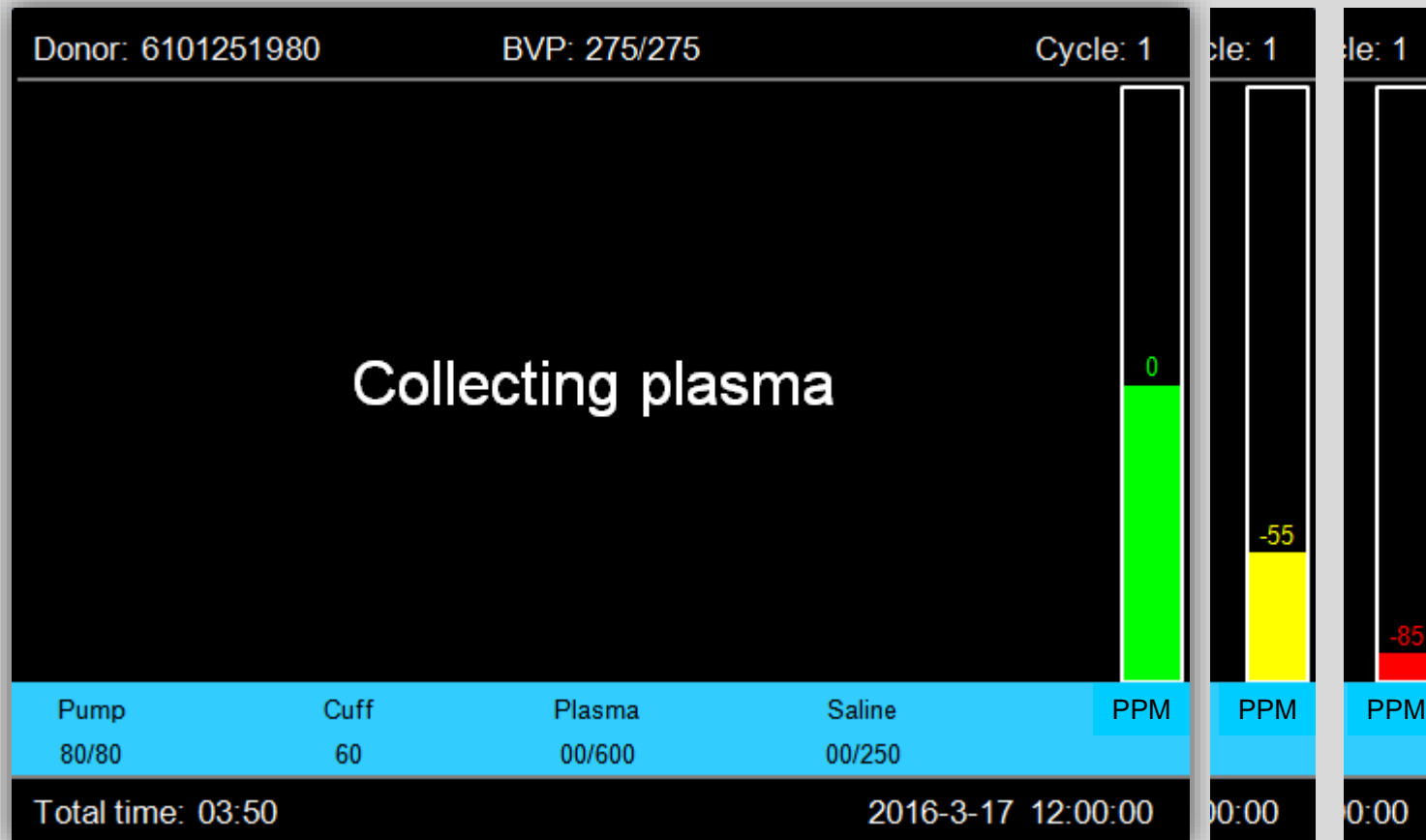
- A built-in WiFi-module enables the machine to exchange information with DMS, like:
  - ID of Operator, who works with machine
  - Disposables released?
  - Machine set-up finished
  - Donor released?
  - Unexpected events
  - All process data and time stamps from procedure
  - ...

# Alarm Indicators on Top and Front





# Alarm Indicator, Examples for Normal, Caution, Warning



- Pressure measured in Donor blood line:
  - **Normal**: -50 to 200 mmHg
  - **Warning limits**:
    - Drawing:  $\leq -80$  mmHg
    - Returning:  $\geq 260$  mmHg
  - **Caution**:
    - -50 to -80 mmHg
    - >200 to 260 mmHg
    - In case of caution-level, pump speed will be reduced automatically



FLOW: **NORMAL**

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PLASMA: **216**


TARGET: **845**

- Donor screens (right & left side) on either side of the machine inform the donor about the status of the procedure


# Flexible Settings

Common parameters	Range of settings	Default setting	Increment of change
Procedure	PPP / FFP	PPP	/
Bowl Optics	On / Off	Yes	/
Draw Pump Speed	20~150ml/min	80	5
Return Pump Speed	20~150ml/min	80	5
Flow Ratio	8:1~22:1	16:1	1
PPP max. Plasma / Cycle	0~300g	300	1
FFP max. Plasma / Cycle	0~200g	100	1
Target Plasma	0~1000g	600	1
Permissible Error	0~50g	3	1
DRAW Cuff Pressure	0~100mmHg	60	1
Venipuncture Cuff Pressure	0~100mmHg	100	1
Saline Compensation	Yes / No	No	/
Saline Volume	0~500ml	250	1
Smart Last Return	Yes / No	Yes	/
Centrifuge Speed	6000~7500rpm	7000	50


# Flexible Assignment of Rights




DIAGNOSTICS



CONFIGURATION



CALIBRATION



PROCEDURE LOG

DRAW

RETURN

EXTENDED FUNCTION

LANGUAGE

SYSTEM TIME

WLAN

SETTINGS

SOFTWARE VERSION

Item	Value	Permission	
		Operator	Manager
DRAW SPEED :	80ml/min	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FLOW RATIO :	16	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CENTRIFUGE SPEED :	7000rpm	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
PERMISSIBLE ERROR :	1g	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
MAX. PLASMA/CYCLE :	300g	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
BOWL OPTICS :	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
PROCEDURE :	PPP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FFP VALUE :	100	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
VENIPUNCTURE C.P. :	100mmHg	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
DRAW C.P. :	60mmHg	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FAST MODE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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Operating instructions:  
Select an item to modify.



Does it deliver?





- 7 Organizations validated Scinomed's plasma collection machine (Source or FFP-mode) in:
  - Denmark
  - Germany
  - Hungary
  - Netherlands
  - 2 centers did not provide data
- Contamination results for:
  - Leukocytes – White Blood Cells
  - Platelets – Platelets
  - Erythrocytes - Red Blood Cells
  - Compared to EDQM Blood Guide limits

- Residual Cell data available from 5 of 7 organizations
  - 4 centers: Source plasma mode (“PPP”)
  - 2 center FFP and 1 leuco-reduced FFP
- Residual cells in source plasma validations by center:

	SPC6+ @Centre 1 (n=45)	SPC6+ @ Centre 2 (n=12)	SPC6+ @ Centre 3 (n=14)	SPC6+ @ Centre 4 (n=45)	EDQM Guide
RBC (10 <sup>9</sup> /l)	0.057778	0.018	0.00143	0.04	<6.0
WBC (10 <sup>9</sup> /l)	0.002778	0.00178	0.00275 (n=4)	0.00225	<0.1
PLT (10 <sup>9</sup> /l)	28.22222	4.59	37.64	20.87	<50

- Mean values accross all centers for source plasma (n=161):

	SPC6+ 4 centres, n=161	EDQM Guide
RBC (10 <sup>9</sup> /l)	0.02930	<6.0
WBC (10 <sup>9</sup> /l)	0.00239 (n=151)	<0.1
PLT (10 <sup>9</sup> /l)	22.8306	<50

- Residual cells in donations with Scinomed's machine are substantially below the limits of EDQM's Blood Guide

- Range by cell-type and center:

Centre and Cell-Type	Range	EDQM-limit
Centre 1 WBC range (10 <sup>9</sup> /l)	0-0.025	< 0,1
Centre 2 WBC range (10 <sup>9</sup> /l)	0-0.0046	< 0,1
Centre 3 WBC range (10 <sup>9</sup> /l)	0-0.004	< 0,1
Centre 4 WBC range (10 <sup>9</sup> /l)	0.00029-0.00770	< 0,1
Centre 1 RBC range (10 <sup>9</sup> /l)	0-0.2	< 6,0
Centre 2 RBC Range (10 <sup>9</sup> /l)	0.008-0.036	< 6,0
Centre 3 RBC Range (10 <sup>9</sup> /l)	0-0.01	< 6,0
Centre 4 RBC Range (10 <sup>9</sup> /l)	0.001-0.15	< 6,0
Centre 1 PLT range (10 <sup>9</sup> /l)	10-70	< 50
Centre 2 PLT range (10 <sup>9</sup> /l)	0-9.17	< 50
Centre 3 PLT Range (10 <sup>9</sup> /l)	20-73	< 50
Centre 4 PLT Range (10 <sup>9</sup> /l)	4.17-51.24	< 50

# Source Plasma: Quality Data Comparison with PCS2

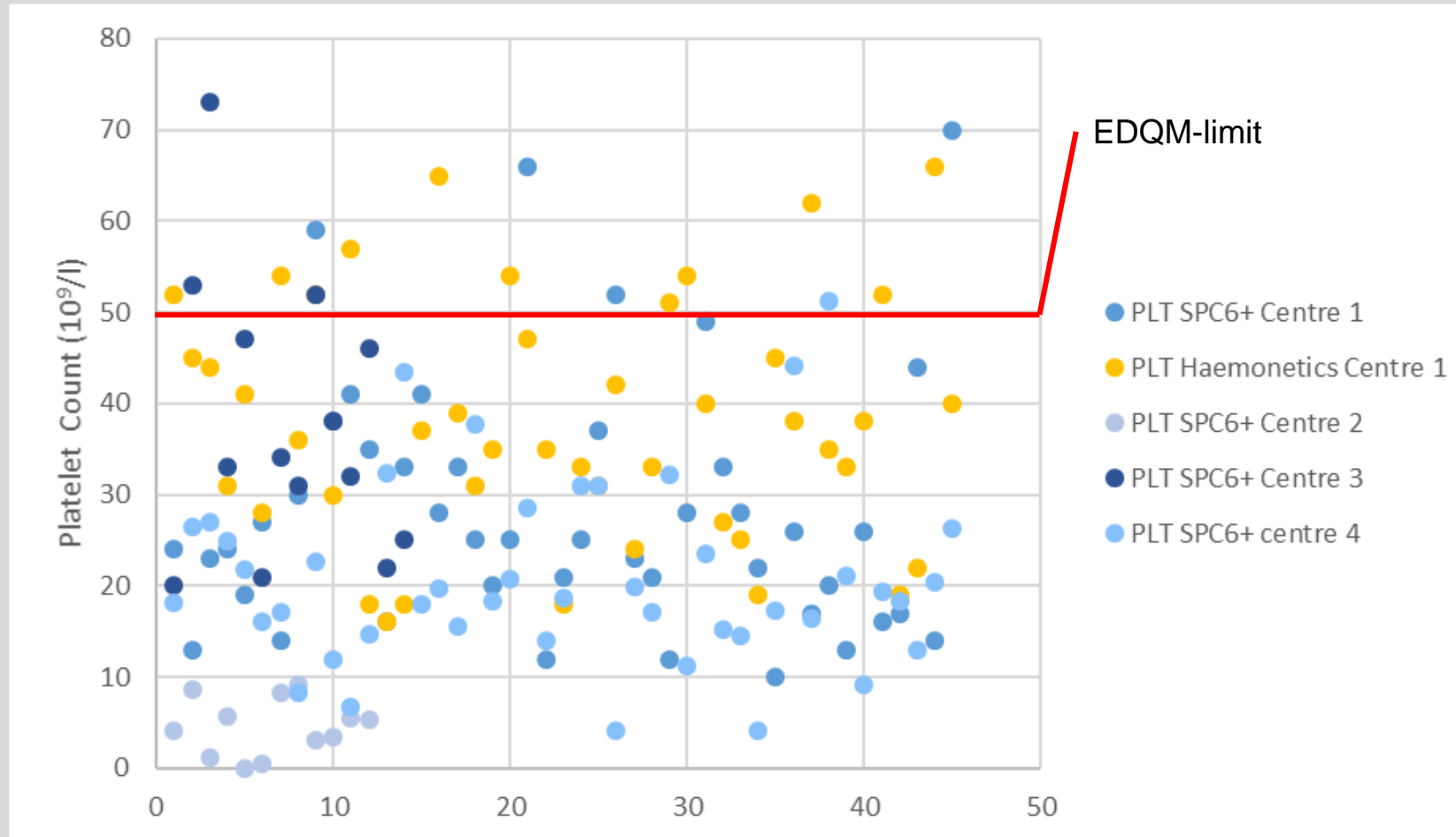
- From one center, data is available for comparison with PCS2
- Data from Kedplasma Hungary, Miskolc
  - 45 donors each on Scinomed machine and Haemonetics PCS2
  - Scinomed Machines in PPP Mode – standard factory settings
- Outcome:

	Scinomed @ Miskolc (n=45)	Haemonetics @ Miskolc (n=45)	Haemonetics @ EDQM- Symposium (Jan. 2019)	EDQM Guide limits
RBC (10 <sup>9</sup> /l)	0.057778	0.466667	0,24	< 6.0 x 10 <sup>9</sup> /L
WBC (10 <sup>9</sup> /l)	0.002778	0.006289	0,0116	< 0.1 x 10 <sup>9</sup> /L
PLT (10 <sup>9</sup> /l)	28.22222	38.0444	33,0	< 50 x 10 <sup>9</sup> /L

- Residual cells in donations with iPCM are...
  - substantially below the limits of EDQM's Blood Guide
  - substantially below PCS2 contamination

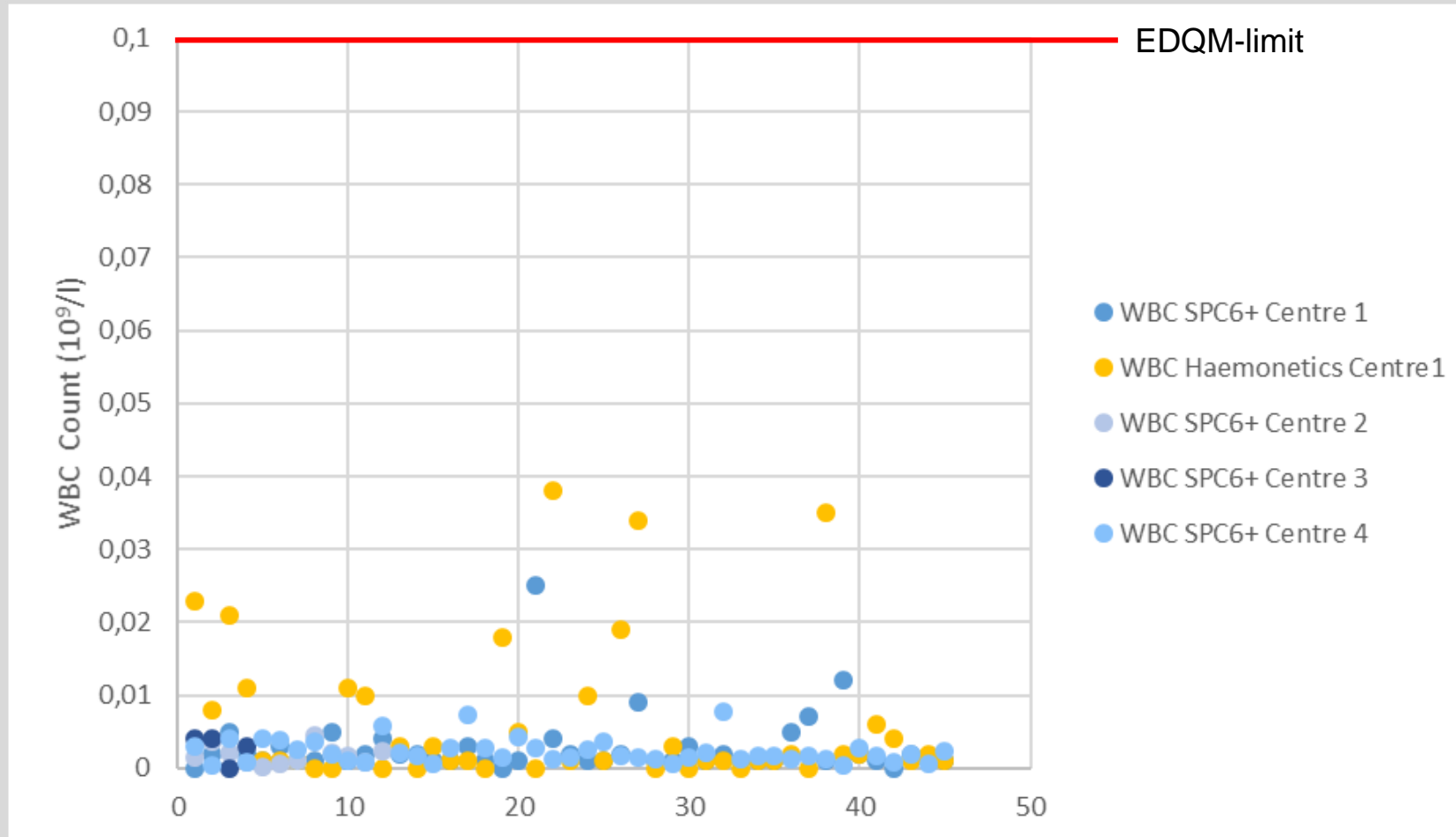


# Source Validation: Residual Platelets



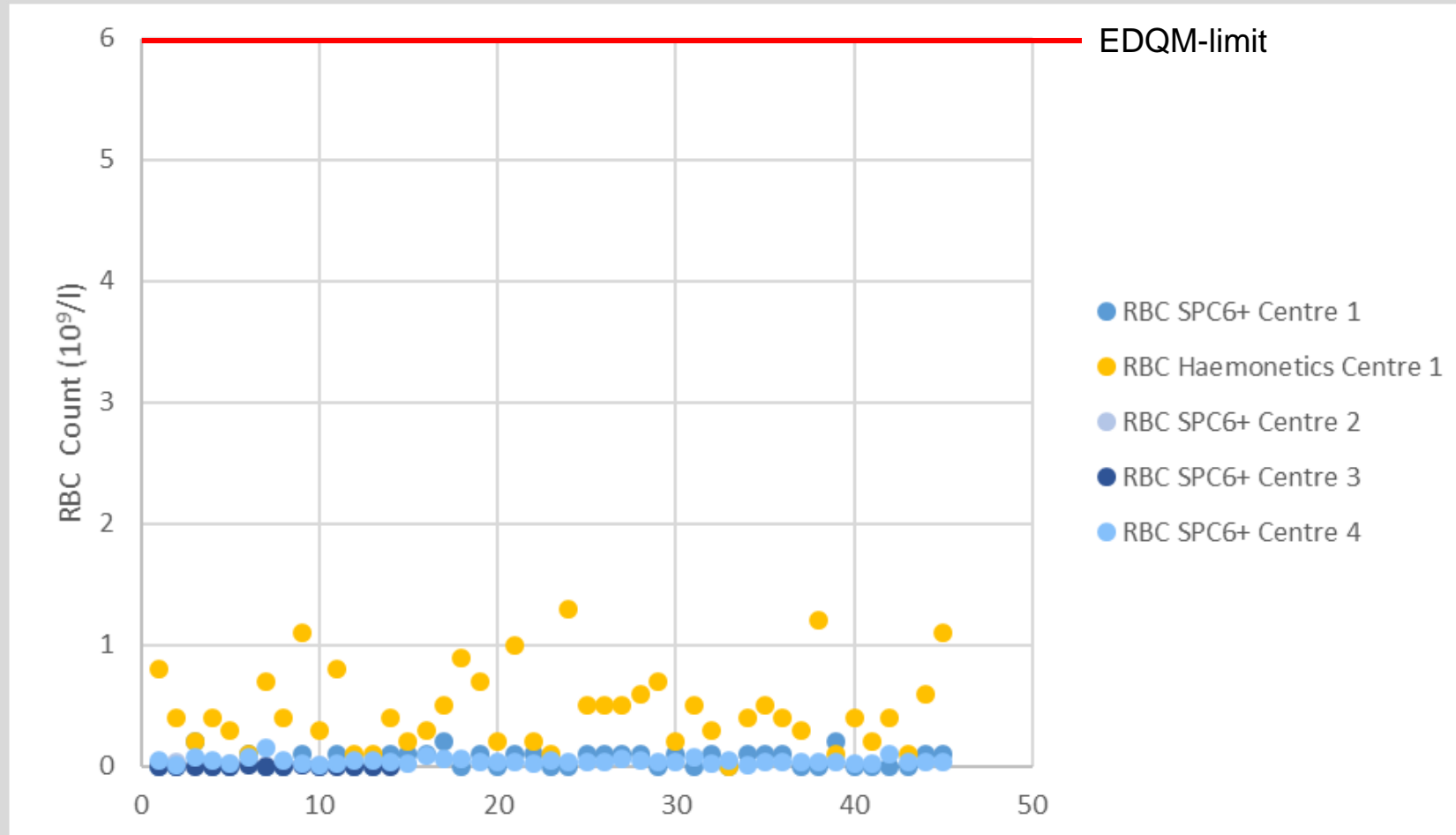
- Few residual platelets are above EDQM-limit

# Source Validation: Residual Leucocytes



- Residual leucocytes are substantially below EDQM-limit

# Source Validation: Residual Red Cells



- Residual red cells are substantially below EDQM-limit

- 2 centers validated in FFP setting:

	SPC6+ @Centre 2 and 5 Mean (n=15)	Range	EDQM Guide* (FFP)
RBC (10 <sup>9</sup> /l)	0.02688	0-0.256	<6.0
WBC (10 <sup>9</sup> /l)	<b>0.00493</b>	<b>0.00083-0.01642</b>	<b>&lt;0.1</b>
PLT (10 <sup>9</sup> /l)	8.7348	0-31	<50

- 1 center provided limited data on FFP-leuco-depleted setting:

	SPC6+ @Centre 5 Mean (n=6)	Range	EDQM Guide* (FFP – leuco- depleted)
RBC (10 <sup>9</sup> /l)	0.0354	0.028-0.042	<6.0
WBC (10 <sup>6</sup> /l)	<b>0.36</b>	<b>0.17-0.85</b>	<b>&lt;1 (per unit)</b>
PLT (10 <sup>9</sup> /l)	20.667	11-33	<50

- Time for collection of 650 – 850 ml (n= 45): 29 - 43 minutes
- Another validation based on 52 donations (cross-over design Scinomed vs. PCS2):
  - 10% higher albumin level (sign.)
  - 10% higher IgG level (ns.)
- Oral communication from a fractionator confirmed...
  - higher yield of IgG in pools from Center with iPCM (than with PCS2)
- Since Feb. 2019: More than 12.000 routine procedures with Scinomed's machine:
  - Preliminary data shows a reduction of donor adverse events of one third compared to PCS2 (hematoma, cardio-vascular)
    - This data will be further evaluated
  - Feedback from donors is positive because...
    - Low noise
    - Hardly any pumping hand needed to maintain blood flow
    - Donor screen



- Scinomed is committed to customer needs, safety and quality
- The new platform delivers:
  - Up-to date and future proof technology
  - Easy installation of sets
  - High quality plasma / low residual cells
  - More comfort & safety to the donor
  - Enhancing GMP-compliance by building in customer's processes in bi-directional communication
  - Optimize plasma center efficiency through data generation
  - And not to forget, the new platform :
    - is the eco-friendliest machine on the market (150 Watt max.)
    - has 2 years of warranty

A man with a beard and dark hair is lying in a white medical chair, smiling and looking towards the camera. He is wearing a light blue patterned shirt. In the background, there is a medical monitor on a stand and some medical equipment on a table.

Thank you for  
your attention!

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